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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,931	02/15/2001	David Ish-Horowicz	7326-122	8177

20583 7590 11/30/2004

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER
KAUFMAN, CLAIRE M

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/783,931	ISH-HOROWICZ ET AL.	
	Examiner	Art Unit	
	Claire M Kaufman	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-32,60,61,99-136 and 138-151* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-32,60,61,101-104,107,109,113-125,129-136 and 142-145* is/are rejected.

7)☐ Claim(s) *99,100,105,106,108,110-112,126-128 and 138-141* is/are objected to.

8)☒ Claim(s) *29-32,60,61,99-136 and 138-151* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to Comply-Sequence*.

DETAILED ACTION

Election/Restrictions

Applicant's statement of election without traverse is noted.

Response to Amendment

The rejection of claims under 35 USC 112, second paragraph, is withdrawn in view of the amendment to the claims or Applicant's arguments.

The rejections of claims under 35 USC 103 as obvious in view of Henrique et al. (Nature, 1995) is withdrawn in view of the 1.132 declaration submitted 9/9/04.

The rejections of claims under 35 USC 103 as obvious in view of Lindsell (Cell, 1995) is withdrawn in view of the amendment to the claims and Applicant's arguments.

Note that the Examiner made a mistake in the previous Office action indicating the objection to the specification occurred on page 87. That should have been page 78. As applicant points out in his response, a preliminary amendment filed 2/15/01 corrected those informalities.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Sequences

This application contains sequence disclosures that are encompassed by the definitions for nucleic and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth in the attached Notice to Comply with Requirements for Patent Applications Containing Nucleic Sequence and/or Amino Acid Sequence Disclosures. In the current application, the CRF and paper copy of the Sequence Listing uses n and/or Xaa. A corresponding explanation must be presented in the <220> to <223> fields of each sequence which presents at least one n or Xaa as required. Both the CRF and paper copy of the Sequence Listing must comply. If the CRF has already complied with this requirement, the paper copy of the Sequence Listing must also be made to comply.

Appropriate correction is required.

Priority

It is noted that provisional application 60/000,589, filed 6/28/95, does not disclose SEQ ID NO:65, but discloses only a PCR fragment of human Delta, which fragment does not comprise SEQ ID NO:65. Therefore, the instant application for the claimed invention does not receive benefit of priority to provisional application 60/000,589. However, for purposes of art for Henrique et al., published 6/29/95, this is publication date is still less than a year from the filing of PCT/US96/11178, filed 6/28/96 to which the instant application receives direct priority.

Response to Amendment

The Declaration under 37 CFR 1.132 filed 09/09/04 is sufficient to overcome the rejection of claims based upon 35 USC 103.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29-32, 60-61, 101-104, 107, 109, 113-125, 129-136 and 142-145 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is directed only to antibodies which bind a vertebrate delta protein encoded by a nucleic acid that hybrizes under high stringency conditions to the human sequence of SEQ ID NO:14 or 26. These sequences do not alone or together encode a full-length human delta protein. Mouse, chicken and Drosophila delta protein are 722, 728 and 832 amino acids long (SEQ ID NO: 12, 2 and 6), respectively. SEQ ID NO:24 is a consensus sequence of human and

mouse delta proteins and represents a full-length sequence. SEQ ID NO:14 has no indicated reading frame and is only 525 bases long, encoding no more than 175 amino acids (corresponding to SEQ ID NO:23). SEQ ID NO: 24 encodes no more than 660 amino acids and appears to comprise gaps in the sequence so there is no one correct reading frame. This rejection, however, does not include wherein the vertebrate delta protein is encoded by a nucleic acid that hybridizes under high stringency conditions to the mouse or chicken sequence of SEQ ID NO:3 and 1, respectively, which are full-length coding sequences. The specification discloses SEQ ID NO:14 and 24, the sequences of the nucleic acid encoding parts of a human delta protein having the sequence of fragments represented by SEQ ID NO:23 and 65-80. While an antibody which binds a vertebrate delta protein comprising sequences SEQ ID NO:23, 65, 66,... or 80, does meet the written description provision of 35 USC 112, first paragraph, antibodies which bind other protein sequences, particularly those sequences encoded by a nucleic acid which the inventors were not in possession of, that is proteins or protein fragments encoded by human sequences other than those encoded by SEQ ID NO:14 or 24, do not have written description. However, the claims are directed to or encompass antibodies binding to sequences that hybridize to SEQ ID NO:14 and 24, including the unknown full-length human sequence, allelic variants, species homologues and splice variants. None of these sequences meets the written description provision of 35 USC 112, first paragraph.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

With the exception of the antibodies referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides encoding full human delta proteins to which the antibodies must bind, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required.

See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an antibody that binds a vertebrate delta protein encoded by a nucleic acid hybridizing under the conditions recited in the claims to a nucleic acid of SEQ ID NO:1, 3 or 24 or wherein the protein comprises SEQ ID NO:2, 12, 23 or 65-80, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Conclusion

Claims 99-100, 105,106, 108, 110-112, 126-128, 138-141 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (571) 272-0873. Dr. Kaufman can generally be reached Monday, Tuesday and Thursday from 8:30AM to 2:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Official papers filed by fax should be directed to (703) 872-9306. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to

avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

Claire M. Kaufman, Ph.D.

Patent Examiner, Art Unit 1646

November 29, 2004

Notice to Comply	Application No.	Applicant(s)	
	09/783,931	ISH-HOROWICZ ET AL.	
	Examiner	Art Unit	
	Claire M Kaufman	1646	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Contains undesignated "Xaa" and "N".

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
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